

**REMARKS**

Claims 1-26, 29-36, 38, 39 and 42-54 are pending in the subject application. Claims 1-26, 29-36, 38-39, 42, 43, 46 and 48-54 stand rejected under newly cited reference Madhani et al (6,786,896). Claims 44 and 45 are allowed. Claims 27, 28, 40, and 41 are allowable. Reconsideration and allowance is requested in view of the remarks herein.

1. 35 U.S.C. §102 Rejection

Claims 1-26, 29-36, 38-39, 42-43, 46 and 48-54 are rejected under 35 U.S.C. §102(b) as being anticipated by Madhani et al (6,786,896). Applicants respectfully traverse.

***CLAIM 1***

Applicants claim, in claim 1, an apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area by a manipulation device. The apparatus comprises a first arm being configured and arranged to rotatably support the penetrating member, a first drive mechanism coupled to the first arm, and a second drive mechanism coupled to the penetrating member. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position. The second drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member.

Thus, Applicants' apparatus includes, (e.g. as shown in Fig. 1), a first arm 120 that rotatably supports penetrating member 50, a first drive mechanism that translates the first arm along the translational axis (as shown by arrow 102). A second drive mechanism further causes the penetrating member to rotate about a long axis of the penetrating member 50 (as shown by arrow 104).

Madhani describes a robotic apparatus having a base positioner 302 and a wrist unit 304. Wrist unit 304 includes an end effector 314 (consisting of a wrist 316 and grippers 318) mounted

to a hollow aluminum instrument shaft 312 through which six cables pass (see col. 10, lines 50-54; col. 17, lines 3-5). The fingers or grippers 318 may be designed to hold needles or could be made as retractors, microforceps, dissecting scissors, blades, etc. (see col. 17, lines 24-26).

The Office points to col. 11, lines 1-7 and asserts that the "first arm" (indicated as 304 in the Office action) is configured and arranged to rotatably support "penetrating member" (indicated as 312 in the Office action).

Applicants respectfully submit that instrument shaft 312 is not a penetrating member in accordance with Applicants' claim 1. Rather, instrument shaft 312 is simply a shaft having a wrist 316 with grippers 318 attached thereto. A penetrating member may be grasped by the grippers 318 in some embodiments.

Further, even if instrument shaft 312 could be interpreted as a penetrating member, the "first arm" 304 is not configured and arranged to rotatably support the instrument shaft 312, and Madhani does not teach or suggest a second drive mechanism that causes the penetrating member to rotate about a long axis of the penetrating member.

As set out in col. 11, lines 1-7 of Madhani, which the Office points to in asserting that Madhani's device provides rotation, the instrument shaft has

two **rotary DOFs about a remote center point 111**. One DOF is rotation about the **axis 0**, which rotation is into and out of the page, indicated at arrow 57. The other DOF is rotation about **axis 1** for the parallelogram and about **axis 1<sub>R</sub>** for the tool shaft 312, indicated by the arcs  $\alpha$  and  $\alpha_R$ , respectively, and the arrow 56.

Thus, the rotation is about a remote center point, not about the long axis of the instrument shaft as set forth in Applicants' claim 1. Applicants, according to Madhani, the tool shaft "can pitch forward and backwards about **axis 1** by  $\pm 60$  degrees, as shown in FIGS. 4 (forward) and 5 (backward) respectively." (col. 11, lines 14-17) This rotation is **not** rotation about the long axis of the tool shaft. **Axis 0** is shown in Figs. 1 and 3, and rotation about axis 0 rotates the tool into

and out of the page, which, as shown in Fig. 1, is a side-to side sweeping rotation along tool shaft 312. This rotation is **not** rotation about the long axis of tool shaft. Rotation about **axis 1<sub>R</sub>** rotates the tool forward and backward about **axis 1<sub>R</sub>**. This rotation is **not** rotation about the long axis of tool shaft.

Thus, the tool shaft is not a penetrating member in accordance with Applicants' disclosure. Further, even if the tool shaft could be considered a penetrating member, any rotation is about a remote center point, not about the long axis of the instrument shaft.

Accordingly, applicants submit that claim 1 is patentable over Madhani. Claims 49 and 52 depend from claim 1 and, likewise, are patentable over Madhani. Reconsideration and withdrawal of the rejection is respectfully requested.

#### ***CLAIM 16***

Applicants claim, in claim 16, an apparatus for placing a proximal portion of a penetrating member in a target area comprising a first arm configured and arranged to support the penetrating member, a first drive mechanism coupled to the first arm and including a linear guide. The first guide mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area. The linear guide is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates.

Applicants respectfully submit that Madhani does not teach or suggest a first arm being configured and arranged to support a penetrating member, and a first drive mechanism including a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates.

According to the Office, Madhani describes a "first arm" 304 and a "penetrating member" 312. As set forth above, element 312, the instrument shaft, is not a penetrating member in accordance with Applicants' disclosure. Thus, Madhani's "first arm" is not configured and arranged to support a penetrating member in accordance with Applicants' claims.

Further, the Office asserts that Madhani's "first drive mechanism (310) includes a linear guide (inherent feature)" on page 3 of the Office action. Applicants respectfully disagree. The Office has not provided a basis in fact or technical reasoning to support a determination that the allegedly inherency characteristic necessarily flows from Madhani's teachings. See *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

As set forth by Applicants, needle deviation from the planned target can result from high needle insertion forces, the forces necessary for penetration into the tissue target, which is greatest at the initial point of entry. Prior devices do not adequately address and prevent this problem.

Applicants prevent needle deviation as the needle is translated to a target site by providing a linear guide that restrains motion of the first arm (which supports the penetrating member) other than in the direction the first arm translates. Thus, as the first arm translates vertically, (e.g. along the y-axis of the penetrating member), thereby moving the penetrating member along the y-axis, the linear guide prevents the first arm (and, thus, the penetrating member) from moving in any other direction than along the y-axis.

There is no teaching or suggestion that Madhani necessarily includes a first drive mechanism having a linear guide. Rather, this teaching comes purely from Applicants' disclosure.

Accordingly, Applicants respectfully submit that claim 16 is patentable over Madhani.

Claims 2-15 and 17-25 depend from claim 16 and, likewise, are patentable over Madhani.

- ✓ Reconsideration and withdrawal of the rejection is respectfully requested.

#### ***CLAIM 26***

Applicants claim, in claim 26, an apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area. The apparatus comprises a first arm configured and arranged to rotatably support the penetrating member, a first drive mechanism coupled to the first arm, and a second drive mechanism coupled to the penetrating member and comprising a gear member secured to the penetrating member. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area. The second drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member. The second drive mechanism comprises a gear member secured to the penetrating member and is mechanically coupled to a motor such that operation of the motor causes the penetrating member to rotate about the long axis.

As set forth above in connection with claim 1, Madhani does not teach or suggest an apparatus wherein rotation along the long axis of the tool shaft is provided. Thus, Madhani does not teach or suggest a second drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member or a gear member secured to the penetrating member and mechanically coupled to a motor such that operation of the motor causes the penetrating member to rotate about the long axis, as set forth in Applicants' claim 26.

Accordingly, claim 26 is patentable over Madhani. Claims 27-28 depend from claim 26 and, likewise, is patentable over Madhani. Reconsideration and withdrawal of the rejection is respectfully requested.

**CLAIM 29**

Applicants claim, in claim 29, an apparatus for placing a proximal portion of a penetrating member in a target area after the apparatus is positioned in proximity to an entry point of an object containing the target area. The apparatus comprises a first arm configured and arranged to rotatably support the penetrating member, a first drive mechanism coupled to the first arm, a second arm coupled to the first drive mechanism, and a second drive mechanism coupled to the penetrating member. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area. The first drive mechanism includes a linear guide that is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates. The second arm is coupled to the first drive mechanism so that the first arm translates towards the second arm. The second drive mechanism is configured and arranged so as to cause the penetrating member to rotate about a long axis of the penetrating member.

Applicants respectfully submit that Madhani does not teach or suggest a first arm and a second arm, the first arm configured and arranged to rotatably support the penetrating member, and the second arm coupled to the first drive mechanism so that the first arm translates towards the second arm as set forth in Applicants' claim 29.

As set forth above in connection with claim 1, Madhani does not teach or suggest an apparatus wherein rotation along the long axis of the tool shaft is provided. Further, Madhani

does not teach or suggest a second arm in addition to first arm (304) coupled to the first drive mechanism (310) so that the first arm (304) translates towards the second arm.

The Office asserts that Madhani describes a first arm 304 and a "second arm" 5. However, element 5 is a micro joint (see col. 5, lines 23-29). Still further, first arm 304 does not translate towards joint 5. Rather, these portions appear to remain at the same distance with relation to each other, e.g. as shown in Figs. 5, 4 and 1. Madhani does not teach or suggest a second arm in accordance with Applicants' claims.

Accordingly, claim 29 is patentable over Madhani. Claims 30-36, 38-41, 50 and 53 depend from claim 29 and, likewise, are patentable over Madhani. Reconsideration and withdrawal of the rejection is respectfully requested.

#### ***CLAIM 42***

Applicants claim, in claim 42, an apparatus for driving a subcutaneous needle so a proximal portion thereof is located in a target area of a body after the apparatus is positioned in proximity to an entry point of the body. The apparatus comprises a first arm configured and arranged to rotatably support the needle, a first drive mechanism coupled to the first arm and including a linear guide, a second arm coupled to the first drive mechanism and including a guide mechanism. The first drive mechanism is configured and arranged to translate the first arm from an initial position to any of a number of other positions spaced from the initial position, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the needle proximal portion is disposed in the target area. The second arm is coupled to the first drive mechanism so that the first arm translates towards the second arm. The linear guide is configured and arranged so as to restrain motion of the first arm other than in the direction the first arm translates. The second drive mechanism is configured and arranged so as to cause the needle to rotate about a long axis of the needle.

As set forth above in connection with claims 1 and 29, Madhani does not teach or suggest an apparatus wherein rotation along the long axis of the tool shaft is provided. Further, Madhani does not teach or suggest a second arm in addition to first arm (304) coupled to the first drive mechanism (310) so that the first arm (304) translates towards the second arm. As further set forth above in connection with claim 29, Madhani does not teach or suggest a second arm coupled to the first drive mechanism so that the first arm translates towards the second arm.

Accordingly, claim 42 is patentable over Madhani. Claims 43, 51 and 54 depend from claim 42 and, likewise, are patentable over Madhani. Reconsideration and withdrawal of the rejection is respectfully requested.

***CLAIM 46***

Applicants claim, in claim 46, a method for localizing a proximal portion of a penetrating member in a target area of a body comprising: supporting the penetrating member from a first arm, positioning the first arm with respect to the body so a long axis of the penetrating member passes through the target area; linearly translating the first arm from an initial position to any of a number of other positions spaced from the initial, thereby also translating the penetrating member proximal portion in a direction towards the target area, wherein one of the any of a number of other positions corresponds to a condition where the penetrating member proximal portion is disposed in the target area; and rotating the penetrating member about the long axis thereof.

As set forth above in connection with claims 1 and 29, Madhani does not teach or suggest an apparatus wherein rotation along the long axis of the tool shaft is provided.

Accordingly, claim 46 is patentable over Madhani.

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**CONCLUSION**

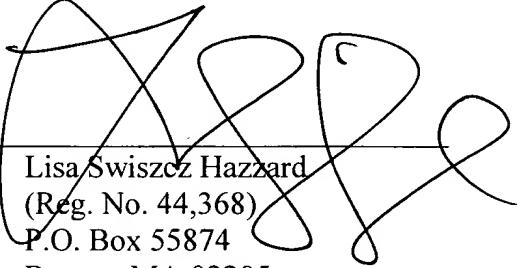
It is respectfully submitted that the subject application is in a condition for allowance.  
Early and favorable action is requested.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,  
Edwards & Angell, LLP

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